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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/787,244

05/16/2001

Narendra Bhadra

M41.1

8097

25742

7590

05/20/2004

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,244

Applicant(s)

BHADRA ET AL.

Examiner

George R Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1-9 are objected to because of the following informalities: In claim 1, line 4, "rood" should be "root". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Brindley (3870051). Although Brindley is coupled to the complete sacral nerve, he still is coupled to both the dorsal and ventral roots since both are located in the sacral nerve and since he uses different stimulation parameters to affect both.

Claims 1-3, 8 and 11-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fang et al (5199430).

Claims 1, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanagho et al (EP 0245547). As stated on page 9, line 45, the pulses may "overlap".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3762

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brindley (or Fang et al or Tanagho).

Brindley (or Fang et al or Tanagho) discloses the claimed invention except for the surface electrode for stimulating the sacral nerve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sacral nerve stimulation system as taught by Brindley (or Fang et al or Tanagho), with the use of an external surface electrode to stimulate the sacral nerve since it was known in the art that sacral stimulation systems use external surface electrodes to stimulate the sacral nerve to provide a non-invasive way of effectively delivering the stimulation.

Claims 5-7, 9, 10, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al.

Fang discloses the claimed invention and that the pulse parameters may be adjusted to excite/activate or block different nerves except for the particulars of the stimulation pulse parameters, such as quasi-trapezoidal or rectangular pulse trains at 20 Hz (claims 5, 6, and 15), an intermittent pulse train at 20 Hz on and off for 1 second each (claims 7 and 16), the second

Art Unit: 3762

electrode pulse having a nominal amplitude of less than 1 ma and a pulse duration of 10-100 usec (claims 9 and 18), and the first electrode pulse having a nominal amplitude of 1 ma and a pulse duration of 350-500 usec (claims 10 and 17) It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulse parameters of the nerve cuff electrodes as taught by Fang, with the particular pulse parameters of claims 5-7, 9, 10 and 15-18, since it was known in the art that cuff electrodes used to stimulate different nerves apply different and particular pulse parameters, such as the pulse parameters in claims 5-7, 9, 10, and 15-18, so that the nerves can be effectively stimulated to activate or block particular diameter nerves and since it is known in the art that different electrode sizes and spacing require different signals to activate or block different nerves.

In addition, Fang provides a clear suggestion that the pulse parameters can be modified to activate or block different nerve fibers. The determination of the most appropriate stimulation parameters, such as the particular pulse parameters of claims 5-7, 9, 10, and 15-18, by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Response to Arguments

Applicant's arguments filed 3/11/04 have been fully considered but they are not persuasive. The argument that the references do not show stimulation of the sacral dorsal roots and therefore do not anticipate or meet the limitations of the claims is not persuasive since the claims do not contain any limitation to stimulating the sacral dorsal roots. The claims only state that there are two electrodes, one coupled to the dorsal root and the other coupled to the sacral root, and a control means to simultaneously apply pulses to the electrodes to cause the bladder to

Art Unit: 3762

contract. The claims do not present any limitations to stimulating the dorsal roots. As stated on page 3 of the previous office action, the references teach coupling of electrodes to the complete sacral nerve, which will couple the electrodes to both the dorsal and ventral roots, and therefore will meet the claimed limitations. In addition, the applicants specification states on page 6, lines 3-5, that although "illustrated as being separated, the dorsal and ventral roots for each nerve are, in fact, normally joined together and their fibers mixed to progress as a single trunk". The references teach applying cuff electrodes with multiple electrodes to the complete sacral nerves, therefore the references teach coupling electrodes to the dorsal and sacral roots. Finally, it is noted that the applicant also claims and teaches the use of surface electrodes to stimulate the dorsal roots, and therefore the electrodes are not directly applied to the dorsal roots but can be applied through other tissue to couple the electrodes to the dorsal root. It is suggested to amend the claims to positively recite the stimulation of the dorsal roots and/or claim the pulse parameters that are simultaneously applied to the dorsal and sacral roots (although, those new limitations will need to be further searched and considered).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3762

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

5/19/04

GRE
May 19, 2004